UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
BROWNSVILLE DIVISION

Belindo Conde Plaintiff, vs. Janssen Pharmaceuticals, Inc., Janssen Research & Development LLC, Johnson & Johnson, Janssen Ortho LLC Defendants.	Civil Action No. _____

COMPLAINT

Belindo Conde (hereinafter "Plaintiff"), by and through undersigned counsel, brings this action seeking judgment against Janssen Pharmaceuticals, Inc., Janssen Reasearch & Development LLC, Janssen Ortho LLC and Johnson & Johnson (collectively referred to as "Defendants") for injuries and damages caused by Plaintiff's ingestion of Invokamet (*canagliflozin-metformin*), a drug in the *glifozin* class.

PARTIES

1. At all relevant times, Plaintiff was a resident of Cameron County, Texas.

2. Upon information and belief, Defendant Janssen Research & Development LLC f/k/a Johnson and Johnson Research and Development LLC (hereinafter referred to as "Janssen R&D") is a limited liability company organized under the laws of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

3. As part of its business, Janssen R&D is involved in the research, development, sales and marketing of pharmaceutical products, including Invokamet.

4. Upon information and belief, and at all relevant times, Janssen R&D was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute the drug Invokamet for use as an oral diabetes medication.

5. Upon information and belief, Defendant Janssen Pharmaceuticals, Inc. f/k/a Janssen Pharmaceutical Inc. f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc. (hereinafter referred to as "Janssen Pharm") is a Pennsylvania corporation with its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

6. As part of its business, Janssen Pharm is involved in the research, development, sales, and marketing of pharmaceutical products, including Invokamet.

7. Janssen Pharm is the holder of the New Drug Application (NDA) for Invokamet.

8. Upon information and belief, and at all relevant times, Janssen Pharm was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Invokamet for use as an oral diabetes medication.

9. Upon information and belief, Defendant Janssen Ortho LLC (hereinafter referred to as "Janssen Ortho") is a limited liability company organized under the laws of Delaware, having its principal place of business at Stateroad 933 Km 0 1, Street Satero, Gurabo, Puerto Rico 00778. Defendant Janssen Ortho is a subsidiary of Johnson & Johnson.

10. As part of its business, Janssen Ortho is involved in the research, development, sales, marketing of pharmaceutical products, including Invokamet.

11. Upon information and belief, and at all relevant times, Janssen Ortho was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the drug Invokamet for use as a diabetes medication.

12. Defendant Johnson & Johnson (hereinafter referred to as "J&J") is a fictitious name adopted by Defendant Johnson & Johnson Company, a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

13. As part of its business, J&J, and its "family of companies," is involved in the research, development, sales, and marketing of pharmaceutical products, including Invokamet.

14. At all times alleged herein, Defendants include and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

15. At all times herein mention, each of the Defendants was the agent, servant, partner, predecessors in interest, and joint venture of each and every of the remaining Defendants herein and was at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, and joint venture.

16. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities the drug Invokamet.

JURISDICTION AND VENUE

17. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds $75,000, exclusive of interest and costs.

18. Venue in this action properly lies in this judicial district pursuant U.S.C. § 1391(b) because, at all times material hereto, a substantial part of the events or omissions giving rise to this claim in this District.

FACTUAL BACKGROUND

19. In August 2014, the United States Food and Drug Administration (FDA) approved Defendants' compound, *canagliflozin-metformin* (Invokamet), for the treatment of type-2 diabetes, making Defendants' drug the first in its class to gain FDA approval that is combined with *metformin*.

20. *Canagliflozin* is a member of *glifozin* class of pharmaceuticals, also known as sodium-glucose cotransporter 2 (SGLT2) inhibitors and is marketed in the United States by Defendants under the name Invokana. Defendants received approval to combine *canagliflozin* with *metformin* to create the first fixed-dose combination of an SGLT2 inhibitor with metformin.

21. Defendant J&J, the parent company of Janssen, is involved in the marketing and branding of Invokamet, and publishes marketing and warnings regarding the product.

22. Defendant J&J also published information touting the strong sales of Invokamet in its corporate reports and in earnings calls.

23. Further, J&J employees had responsibility for overseeing promotion strategies for the drug Invokamet.

24. Materials including advertisements, press releases, website publications, and other communications regarding Invokamet are part of the labeling of the drug, and could be altered without prior FDA approval.

25. Defendant J&J had the ability and the duty to improve the labeling of Invokamet to warn of the propensity of the drug to cause diabetic ketoacidosis, renal injury, increased chance of

lower limb amputation, renal failure, severe infection, etc.

26. Defendant J&J so substantially dominates and controls the operations of Janssen and Janssen R&D that it could have required them to make changes to the safety label of the drug Invokamet.

27. J&J employees hold key roles in the design, development, regulatory approval, manufacturing, distribution, and marketing of Invokamet and direct these activities on behalf of J&J, Janssen, and Janssen R&D.

28. In fact, J&J so substantially dominates and controls the operations of Janssen and Janssen R&D, that the entities are indistinct for purposes of this litigation such that Janssen and Janssen R&D should be considered agents or departments of J&J, and J&J is their alter-ego.

29. Defendant Janssen, a wholly owned subsidiary of J&J, acquired the marketing right to Invokamet in North America, and marketed, advertised, distributed, and sold Invokamet in Texas and New Jersey and the remainder of the United States.

30. In August 2014, the FDA approved Invokamet as an adjunct to diet and exercise for the improvement of glycemic control in adults with Type 2 Diabetes.

31. As part of its marketing approval of *canagliflozin*, the FDA required the Defendants to conduct five post-marketing studies: a cardiovascular outcomes trial; an enhanced pharmaco-vigilance program to monitor for malignancies, serious cases of pancreatitis, severe hypersensitivity reactions, photosensitivity reactions, liver abnormalities, and adverse pregnancy outcomes; a bone safety study; and two pediatric studies under the Pediatric Research Equity Act (PREA), including a pharmacokinetic and pharmacodynamics study and a safety and efficacy study.

32. In an effort to increase sales and market share, Defendants have aggressively

marketed and continue to aggressively market Invokamet to doctors and directly to patients for off-label purposes, including, but not limited to weight loss, reduced blood pressure, kidney benefits, cardiovascular benefits, and for use in Type I diabetics.

33. Defendants also, through their marketing materials, misrepresented and exaggerated the effectiveness of Invokamet, both as to its ability to lower glucose, and its benefit for non-surrogate measures of health, such as reducing adverse cardiovascular outcomes.

34. Defendants' marketing campaign willfully and intentionally misrepresented the risks of Invokamet and failed to warn about the risks of diabetic ketoacidosis, kidney failure, sepsis, and other injuries.

35. Defendant Janssen Pharm acquired the marketing rights to Inbokamet in North America, and in collaboration with Defendant Janssen R&D, submitted Invokamet's NDA for approval.

36. Defendant Janssen Ortho manufactures Invokamet for distribution to consumers throughout the United States, including Texas.

37. Upon information and belief, all Defendants participated in designing, developing, researching, manufacturing, marketing, distributing and selling Invokamet.

38. Invokana/Invokamet are some of Defendants' top selling drugs, with annual sales exceeding $1 billion.

39. On July 5, 2017, the FDA required Defendants to add a box warning to Invokamet to alert patients of an increased chance of lower limb amputation from use of Invokamet.

40. Additionally, the FDA has received a significant number of adverse event reports linking Invokamet to kidney injuries, including renal failure, renal impairment, renal insufficiency, and renal failure.

41. Despite Defendants' knowledge of the increased risk of severe injury among Invokamet users, Defendants did not warn patients but instead continued to defend and aggressively promote Invokamet, mislead physicians and the public, and minimize unfavorable findings.

42. Despite their knowledge of data indicating that Invokamet use is causally related to the development of increased chance of lower limb amputation, diabetic ketoacidosis, kidney failure, stroke, and heart attack, Defendants promoted and marketed Invokamet as safe and effective for persons such as Plaintiff throughout the United States, including Texas and New Jersey.

43. Though Defendants did nothing to alert United States consumers, and health care professionals of the risks associated with Invokamet, they did send "Dear Doctor" letters warning of Invokana's (Invokamet's sister-drug) ketoacidosis risk to healthcare professionals in Canada, and Australia in July 2015, after those countries' respective drug regulatory agencies issued safety announcements concerning Invokana. No such letter was sent to Plaintiff's healthcare providers.

44. Despite clear signals in the available data, Defendants did not tell consumers, healthcare professionals, or the scientific community about the dangers of Invokamet.

45. Defendants' original and current labeling and prescribing information:

a. Failed to investigate, research, study and define, fully and adequately, the safety profile of Invokamet;

b. Failed to provide adequate warnings, about the true safety risks associated with the use of Invokamet;

c. Failed to warn that chances for lower limb amputation were increased with Invokamet;

d. Failed to include "BOXED WARNING" about lower limb amputation associated with Invokamet; and

e. Failed to a "BOLDED WARNING" about lower limb amputation associated with Invokamet.

46. Consumers, including Plaintiff, who have used Invokamet for treatment of diabetes, have several alternative safer products available for treatment. SGLT-2 inhibitors, including Invokamet, are the only class of drugs which utilize the mechanism of expelling significant quantities of glucose through the kidneys to lower blood-glucose.

47. Defendants knew of the significant risk of severe injury caused by ingestion of Invokamet. However, Defendants did not warn or did not adequately and sufficiently warn consumers, including Plaintiff, or the medical community of the severity of such risks.

48. To the contrary, Defendants conducted nationwide sales and marketing campaigns to promote the sale of Invokamet and willfully deceived Plaintiff, his/her health care professionals, the medical community, and the general public as to the health risks and consequences of the use of Invokamet.

49. Consumers of Invokamet and their physicians relied on the Defendants' false representations and were misled as to the drug's safety, and as a result have suffered injuries including lower limb amputations, diabetic ketoacidosis, kidney failure, sepsis, cardiovascular problems, stroke, and the life-threatening complications thereof.

50. Plaintiff had several alternative and safer methods to treat his diabetes, including diet and exercise and other diabetes medications.

51. As a direct result, in 2015, Plaintiff was prescribed and began taking Invokamet, primarily to treat diabetes.

52. Plaintiff ingested and used Invokamet as prescribed and in a foreseeable manner.

53. The Invokamet used by Plaintiff was provided to him in a condition substantially the same as the condition in which it was manufactured and sold.

54. Plaintiff agreed to initiate treatment with Invokamet in an effort to reduce his/her blood sugar. In doing so, Plaintiff relied on claims made by Defendants that Invokamet was safe and effective for the treatment of diabetes.

55. Instead, Invokamet can cause severe injuries, including heart attack, stroke, renal failure, renal impairment, renal insufficiency, kidney injury and diabetic ketoacidosis.

56. After beginning treatment with Invokamet, and as a direct and proximate result thereof, on or about March 15, 2016, Plaintiff had to have his left fourth toe removed following in 2017 with the amputation of his leg as a result of complicaitons resulting from taking Invokamet.

57. As a result of his injuries, Plaintiff was hospitalized and required substantial medical treatment.

58. At the time of Plaintiff's injuries, Plaintiff regularly ingested the Invokamet as prescribed by his doctor.

59. Defendants knew or should have known the risks associated with the use of Invokamet, including the risk of lower limb amputation.

60. The development of Plaintiff's injuries was preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life-threatening risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of Invokamet. This conduct, as well as the product defects complained of herein, were substantial factors in bringing about and exacerbating Plaintiff's injuries.

61. Plaintiff's injuries were a reasonably foreseeable consequence of Defendants' conduct and Invokamet's defects.

62. At all times material hereto, Defendants, by and through their agents, servants and employees, negligently, recklessly and carelessly marketed, distributed and sold Invokamet without adequate instructions or warning of its serious side effects and unreasonably dangerous risks.

63. Plaintiff would not have used Invokamet had Defendants properly disclosed the risks associated with the drug. Thus, had Defendants properly disclosed the risks associated with Invokamet, Plaintiff would have avoided the risk of developing the injuries complained of herein by not ingesting Invokamet.

64. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with ingesting Invokamet.

65. As a result of Defendants' actions, Plaintiff and his/her prescribing physicians were unaware, and could not reasonably have known or learned through reasonable diligence, that Plaintiff had been exposed to the risks identified herein, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

66. As a direct and proximate result of Defendants' negligence, wrongful conduct, and the unreasonably dangerous and defective characteristics of Invokamet, Plaintiff suffered severe and permanent physical and emotional injuries. Plaintiff has endured pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment which will continue in the future. Plaintiff seeks actual, compensatory, and punitive damages from Defendants.

67. Plaintiff has suffered from mental anguish from the knowledge that he/she may suffer life-long complications as a result of the injuries caused by Invokamet.

CAUSES OF ACTION

Count 1 – Strict Liability

68. Plaintiff restates the allegations set forth above as if fully rewritten herein.

69. At the time of Plaintiff's injuries, Defendants' pharmaceutical drug Invokamet was defective and unreasonable dangerous to foreseeable consumers, including Plaintiff.

70. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed Invokamet, including the Invokamet used by Plaintiff, which was in a defective and unreasonably dangerous condition.

71. Defendants expected Invokamet to reach, and it did in fact reach, Plaintiff without substantial change in the condition in which it was manufactured and sold by the Defendants.

72. At all times relevant hereto, Defendants' Invokamet was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition and was dangerous for use by the public and in particular by Plaintiff.

73. At all times relevant to this action, Invokamet, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by the Defendants, was defective in design and formulation in one or more of the following particulars:

a. When placed in the stream of commerce, Invokamet contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the drug;

b. When placed in the stream of commerce, Invokamet was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with the treatment of diabetes;

c. Invokamet was insufficiently tested;

d. Invokamet caused harmful side effects that outweighed any potential utility;

e. Defendants were aware at the time Invokamet was marketed and sold that ingestion of Invokamet would result in an increased risk of heart attack, renal failure, renal impairment, renal insufficiency, ketoacidosis, and other severe injuries;

f. Inadequate post-marketing surveillance;

g. There were safer alternative designs and formulations that were not utilized; and

h. Inadequate warnings or instructions, as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects, including kidney injuries, heart attack, stroke, and diabetic ketoacidosis, as well as other severe and personal injuries.

74. Invokamet was defective, failed to perform safely, and was unreasonably dangerous when used by ordinary consumers, including Plaintiff, as intended and in a reasonably foreseeable manner.

75. Invokamet, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in its design or formulation, in that it was unreasonably dangerous, and its foreseeable risks exceeded the alleged benefits associated with Invokamet's design or formulation.

76. Invokamet, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in design or formulation in that it posed a greater likelihood of injury than other diabetes drugs and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

77. At all times relevant to this action, Defendants knew or had reason to know that Invokamet was in a defective condition and was inherently dangerous and unsafe when used in the manner instructed, provided, and/or promoted by Defendants. Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain supply, provide proper warnings, and otherwise ensure that Invokamet was not

unreasonably dangerous for its normal, common, intended use, or for use in a form and manner instructed and provided by Defendants.

78. When Defendants placed Invokamet into the stream of commerce, they knew it would be prescribed to treat diabetes, and they marketed and promoted Invokamet as safe for treating diabetes.

79. Plaintiff was prescribed, purchased, and used Invokamet. Plaintiff used Invokamet for its intended purpose and in the manner recommended, promoted, marketed, and reasonably anticipated by Defendants.

80. Neither Plaintiff nor his/her health care professionals, by the exercise of reasonable care, could have discovered the defects and risks associated with Invokamet before Plaintiff's ingestion of Invokamet.

81. The harm caused by Invokamet far outweighed its benefit, rendering Invokamet more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products. Defendants could have designed Invokamet to make it less dangerous. When Defendants designed Invokamet, the state of the industry's scientific knowledge was such that a less risky design was attainable.

82. At the time Invokamet left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without substantially impairing the reasonably anticipated or intended function of Invokamet. This was demonstrated by the existence of other diabetes medications that had a more established safety profile and a considerably lower risk profile.

83. At all times relevant, Defendants knew or should have known that the warnings or instructions for Invokamet were inadequate to warn of the nature, likelihood or severity of the risks

associated with the drug.

84. Defendants' defective design of Invokamet was willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of Invokamet.

85. Defendants' conduct was motivated by greed and the intentional decision to value profits over the safety and well-being of the consumers of Invokamet.

86. The defects in Invokamet were substantial and contributing factors in causing Plaintiff's injuries. But for Defendants' acts and omissions, Plaintiff would not have suffered the injuries complained of herein.

87. Due to the unreasonably dangerous condition of Invokamet, Defendants are liable for Plaintiff's injuries.

88. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of Invokamet, including Plaintiff, with knowledge of the safety problems associated with Invokamet, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

89. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered personal and economic injuries. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring,

and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory, treble and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

Count 2 – Manufacturing Defect

90. Plaintiff restates the allegations set forth above as if fully rewritten herein.

91. Invokamet was designed, manufactured, marketed, promoted, sold and introduced into the stream of commerce by Defendants.

92. When it left the control of Defendants, Invokamet was expected to, and did reach Plaintiff without substantial change from the condition in which it left Defendants' control.

93. Invokamet was defective when it left Defendants' control and was placed in the stream of commerce, in that there were foreseeable risks that exceeded the benefits of the product and/or that it deviated from the product specifications and/or applicable requirements and posed a risk of serious injury and death.

94. Specifically, Invokamet was more likely to cause serious injuries, including increased chance of lower limb amputations, heart attack, stroke, renal failure, renal impairment, renal insufficiency and ketoacidosis, than other diabetes medications.

95. Plaintiff used Invokamet in substantially the same condition it was in when it left the control of Defendants and any changes or modifications were foreseeable by Defendants.

96. Plaintiff or his/her healthcare providers did not misuse or materially alter their Invokamet.

97. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of Invokamet, including Plaintiff, with knowledge of the safety problems associated with Invokamet, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

98. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered personal and economic injury. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory, treble and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

Count 3 – Design Defect.

99. Plaintiff restates the allegations set forth above as if fully rewritten herein.

100. Invokamet was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by Plaintiff.

101. Defendants placed Invokamet into the stream of commerce with wanton and reckless disregard for the public safety.

102. Invokamet was in an unsafe, defective, and inherently dangers condition.

103. Invokamet contains defects in its design which render the drug dangerous to consumers, such as Plaintiff, when used as intended or as a reasonably foreseeable to Defendants. The design defects render Invokamet more dangerous than other diabetes medications and cause an unreasonable increased risk of injury, including but not limited to heart attack, renal failure, renal impairment, renal insufficiency and ketoacidosis.

104. Invokamet was in a defective condition and unsafe, and Defendants knew, had reason to know, or should have known that Invokamet was defective and unsafe, even when used as instructed.

105. The nature and magnitude of the risk of harm associated with the design of Invokamet, including the risk of lower limb amputation, heart attack, stroke, renal failure, renal impairment, renal insufficiency and ketoacidosis, is high in light of the intended and reasonably foreseeable use of Invokamet.

106. The risks of harm associated with the design of Invokamet are higher than necessary.

107. It is highly unlikely that Invokamet users would be aware of the risks associated with Invokamet through either warnings, general knowledge or otherwise, and Plaintiff specifically was not aware of these risks, nor would he/she expect them.

108. The design did not conform to any applicable public or private product standard that was in effect when the Invokamet left Defendants' control.

109. Invokamet design is more dangerous than a reasonably prudent consumer would expect when in its intended or reasonably foreseeable manner. It was more dangerous than Plaintiff expected.

110. The intended or actual utility of Invokamet is not of such benefit or to justify the risk of heart attack, stroke, renal failure, renal impairment, renal insufficiency and ketoacidosis.

111. At the time Invokamet left Defendants' control, it was both technically and economically feasible to have an alternative design that would not cause lower limb amputation, heart attack, renal failure, renal impairment, renal insufficiency and ketoacidosis, or an alternative design that would have substantially reduced the risk of these injuries.

112. It was both technically and economically feasible to provide a safer alternative product that would have prevented the harm suffered by Plaintiff.

113. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendant's outrageous conduct warrants an award of punitive damages.

114. The unreasonably dangerous nature of Invokamet caused serious harm to Plaintiff.

115. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered personal and economic injuries. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other

losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory, treble and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

Count 4 – Failure to Warn

116. Plaintiff restates the allegations set forth above as if fully rewritten herein.

117. Defendants had a duty to warn Plaintiff and his/her healthcare providers regarding the nature, likelihood, and severity of risks associated with Invokamet, including but not limited to lower limb amputation, heart attack, stroke, renal failure, renal impairment, renal insufficiency and ketoacidosis.

118. Defendants' knew, or in the exercise of reasonable care, should have known about the risk of heart attack, stroke, renal failure, renal impairment, renal insufficiency and ketoacidosis.

119. Defendants failed to provide warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of lower limb amputation, heart attack, stroke, renal failure, renal impairment, renal insufficiency and ketoacidosis, in light of the likelihood that its product would case these injuries.

120. Defendants failed to update warnings based on information received from product surveillance after Invokamet was first approved by the FDA and marketed, sold, and used in the United States and throughout the world.

121. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to individuals using Invokamet after FDA approval.

122. When it left Defendants' control, Invokamet was defective and unreasonably dangerous for failing to adequately warn of the risk of heart attack, stroke, renal failure, renal impairment, renal insufficiency and ketoacidosis.

123. Plaintiff used Invokamet for its approved purpose and in a manner normally intended and reasonably foreseeable by Defendants.

124. Plaintiff and Plaintiff's healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived their danger because the risks were not open or obvious.

125. Defendants, as the manufacturers and distributors of Invokamet, are held to the level of knowledge of an expert in the field.

126. The warnings that were given by Defendants failed to properly warn physicians of the risks associated with Invokamet, subjecting Plaintiff to risks that exceed the benefits to the Plaintiff. Plaintiff, individually and through his/her physicians, reasonably relied upon the skill, superior knowledge and judgment of Defendants.

127. Defendants had a continuing duty to warn Plaintiff and his/her prescriber of the dangers associated with Invokamet.

128. Had Plaintiff or his/her healthcare provider received adequate warnings regarding the risks associated with the use of Invokamet, Plaintiff would not have used it.

129. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public.

Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

130. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered personal and economic injuries. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory, treble and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

Count 5 – Negligence.

131. Plaintiff restates the allegations set forth above as if fully rewritten herein.

132. At all times relevant times, Defendants had a duty to use reasonable care to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of Invokamet.

133. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers

of Invokamet to cause or increase the harm of diabetic ketoacidosis, kidney failure, increased chance of lower limb amputation, myocardial infarction, and the life-threatening complications of those conditions.

134. Defendants had a duty to exercise due care and avoid unreasonable risk of harm to others when developing and selling Invokamet. Defendants knew or should have known that some patients would develop serious injuries that were not adequately warned about, including ketoacidosis, kidney injury, renal sufficiency, kidney failure, increased chance of lower limb amputation, and myocardial infarction, and these injuries were foreseeable.

135. Plaintiff did not know the nature and extent of the injuries that could result from Invokamet and was misinformed about the benefits of Invokamet and could not have discovered this information independently.

136. At all times herein mentioned, Defendants breached its duty of care by failing to exercise reasonable and ordinary care and negligently and carelessly manufacturing, designing, formulating, distributing, compounding, producing, processing, assembling, inspecting, distributing, marketing, labeling, packaging, preparing for use, and selling Invokamet, and failing to adequately test and warn of the risks and dangers of Invokamet.

137. Despite the fact that Defendants knew or should have known that Invokamet caused unreasonable, dangerous side effects, Defendants continued to market Invokamet to consumers including Plaintiff, when there were safer alternative methods available.

138. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered personal and economic injuries. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue

to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

Count 6 – Breach of Implied Warranty

139. Plaintiff restates the allegations set forth above as if fully rewritten herein.

140. Defendants impliedly warranted to Plaintiff that Invokamet was of merchantable quality and safe and fit for the use which it was intended.

141. The product did not conform to representations made by the manufacturer.

142. Plaintiff reasonably relied entirely on the skill, judgment, and implied warranty of the Defendants when using Invokamet.

143. As a result, Plaintiff used Defendants' product as it was warranted and intended.

144. Invokamet was not of merchantable quality, as warranted by Defendants because it was dangerous when used as intended and can cause severe injuries to consumers.

145. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered personal and economic injuries. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue

to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

Count 7 – Breach of Express Warranty.

146. Plaintiff restates the allegations set forth above as if fully rewritten herein.

147. Defendants expressly warranted to Plaintiff by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts, marketing, and other written materials intended for physicians and the public that Invokamet is safe, effective, fit and proper for its intended use, of merchantable quality, had been adequately tested, contained adequate warnings, and was effective.

148. The "Warnings and Precautions" section of the Invokamet prescribing information purports to expressly describe the relevant and material side-effects that Defendants knew or should have known about.

149. In particular the Consumer Medication Guide did not include any language that would suggest Invokamet has been associated with diabetic ketoacidosis, kidney failure, increased chance of lower limb amputation, blood infections, kidney infections, or myocardial infarction.

150. Plaintiff's physician prescribed Invokamet and Plaintiff consumed Invokamet reasonably relying on these warranties. Neither Plaintiff, nor Plaintiff's physician, could not have learned independently that Janssen was false and misleading.

151. The product did not conform to representations made by the manufacturer.

152. Defendants knew or should have known Plaintiff would rely on its warranties.

153. Plaintiff reasonably relied on the skill, judgment, representations, and foregoing express warranties of Defendants.

154. The warranties and representations are false. Invokamet can cause diabetic ketoacidosis, kidney failure, blood infections, kidney infections, increased chance of lower limb amputation, and myocardial infarction.

155. Invokamet does not conform to Defendants' express representations; therefore, Janssen has breached the express warranties.

156. The breach of express warranties by Defendants was a foreseeable, direct, and proximate cause of Plaintiff's injuries and damages as alleged herein.

157. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered personal and economic injuries. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

Count 8 – Negligent Misrepresentation

158. Plaintiff restates the allegations set forth above as if fully rewritten herein.

159. Defendants owed a duty in all of their undertakings, including the dissemination of information concerning Invokamet, to exercise reasonable care to ensure they did not create unreasonable risks of personal injury to others.

160. Defendants disseminated to health care professionals and consumers — through published labels, marketing materials, and otherwise — information that misrepresented the properties and effects of Invokamet with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe or ingest Invokamet.

161. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of Invokamet, knew or reasonably should have known that health care professionals and consumers of Invokamet rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of prescribing or ingesting Invokamet.

162. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of Invokamet were accurate, complete, and not misleading. As a result, Defendants disseminated

information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

163. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors of Invokamet, knew or reasonably should have known that health care professionals would write prescriptions for Invokamet in reliance on the information disseminated by Defendants, and that the patients receiving prescriptions for Invokamet would be placed in peril of developing serious and potential life threatening injuries if the information disseminated by Defendants and relied upon was materially inaccurate, misleading, or otherwise false.

164. From the time Invokamet was first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed, and up to the present, Defendants failed to disclose material facts regarding the safety of Invokamet. Defendants made material misrepresentations to Plaintiff, his health care professionals, the healthcare community, and the general public, including:

a. stating that Invokamet had been tested and found to be safe and effective for the treatment of diabetes;

b. concealing, misrepresenting, and actively downplaying the severe and life-threatening risks of harm to users of Invokamet, when compared to comparable or superior alternative drug therapies; and

c. misrepresenting Invokamet risk of unreasonable, dangerous, adverse side effects.

165. Defendants made the foregoing representations without any reasonable ground for believing them to be true.

166. These representations were made directly by Defendants, their sales representative, and other authorized agents, and in publications and other written materials directed to health care professionals, medical patients, and the public.

167. Defendants made these representations with the intent to induce reliance thereon, and to encourage the prescription, purchase, and use of Invokamet.

168. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Plaintiff, the truth regarding Defendants' claims that Invokamet had been tested and found to be safe and effective for treating diabetes.

169. The misrepresentations made by Defendants, in fact, were false and known by Defendants to be false at the time the misrepresentations were made.

170. Defendants failed to exercise ordinary care in making their representations concerning Invokamet and in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of Invokamet.

171. Defendants engaged in a nationwide marketing campaign, over-promoting Invokamet in written marketing literature, in written product packaging, and in direct-to consumer advertising via written and internet advertisements and television commercial ads. Defendants' over-promotion was undertaken by touting the safety and efficacy of Invokamet while concealing, misrepresenting, and actively downplaying the serious, severe, and life-threatening risks of harm to users of Invokamet, when compared to comparable or superior alternative drug therapies. Defendants negligently misrepresented Invokamet's risk of unreasonable and dangerous adverse side effects.

172. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of Invokamet, including Plaintiff. Defendants had knowledge of the safety problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

173. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff personal and economic injuries. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

Count 9 – Fraudulent Misrepresentation

174. Plaintiffs adopt by reference each and every paragraph of this Complaint as if fully rewritten herein.

175. Defendants intentionally and fraudulently misrepresented the safety and efficacy of Invokamet in the product label.

176. Specifically, Defendants intentionally and fraudulently:

a. Provided a "Warnings and Precautions" section of the Invokamet prescribing information that purports to expressly describe the relevant and material potential side-effects that Defendants knew or should have known about, but in which material and relevant information was fraudulently withheld from this section;

b. Provided Consumer Medication Guide that expressly indicates "What is the most important information I should know about Invokamet?" and "What are the possible side effects of Invokamet?" and "General information about

the safe and effective use of Invokamet" and fraudulently omits information Invokamet has been associated with lower limb amputation, diabetic ketoacidosis, kidney failure, stroke, or cardiovascular events;

c. On information and belief, each and every advertisement and marketing channel fraudulently omits information about the risks of Invokamet and overstates the benefits;

d. Failed to disclose that Invokamet was not as safe and effective as other diabetes drugs;

e. Failed to disclose that Invokamet does not result in safe and more effective diabetes treatments than other available drugs;

f. Failed to disclose that the risk of harm associated with Invokamet was greater than the risk of harm associated with other diabetes drugs;

g. Failed to disclose that Defendants knew that Invokamet was not adequately tested;

h. Failed to disclose that testing had revealed unreasonably high risk of injury;

i. On information and belief, failed to disclose that Defendants intentionally withheld safety information from the FDA; and

j. Affirmatively asserted that Invokamet was safe and effective.

177. Defendants knew that their representations were false, yet they willfully, wantonly and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of Invokamet to Plaintiff, other consumers, Plaintiff's physicians, and the medical community.

178. The representations were made by the Defendants with the intent that doctors and patients, including Plaintiff and his/her physicians, rely upon them.

179. Defendants' representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, Plaintiff's physicians, and the medical community to induce and encourage the sale of Invokamet.

180. Defendants J&J, Janssen, and Janssen R&D, in advertisements through their respective websites, and press releases issued by the respective defendants, stated that the drug

Invokamet was generally well tolerated and safe for use, and was not likely to cause side effects other than the ones listed – these listed side effects did not include diabetic ketoacidosis, renal injury or renal failure, stroke, or cardiovascular events. Plaintiff, his/her doctors, and other relied upon these representations.

181. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered from osteomyelitis and other related health complications. Plaintiff has incurred medical and related expenses. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering as well as the injuries and damages alleged herein

Count 10 – Unjust Enrichment.

182. Plaintiff restates the allegations set forth above as if fully rewritten herein.

183. Plaintiff conferred a benefit on Defendants by purchasing Invokamet.

184. Plaintiff, however, did not receive a safe and effective drug for which he paid.

185. It would be inequitable for Defendants to retain this money, because Plaintiff did not, in fact, receive a safe and efficacious drug.

186. By its conscious wrongdoing, Defendants has been unjustly enriched at the expense of Plaintiff, who hereby seeks the disgorgement and restitution of the Defendants' wrongful profits, revenue, and benefits, to the extent, and in the amount, deemed appropriate by the Court, and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

187. Plaintiff restates the allegations set forth above as if fully rewritten here. 253. Plaintiff used Invokamet and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protections laws.

188. Defendants used unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, uses, benefits or quantities that they do not have:

b. Advertising goods or services with the intent not to sell them as advertised; and

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

189. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of Invokamet.

190. Defendants uniformly communicated the purported benefits of Invokamet while failing to disclose the serious and dangerous side effects related to the use of Invokamet and of the true state of Invokamet's regulatory status, its safety, its efficacy, and its usefulness. Defendants made these representations to physicians, the medical community at large, and to patients and consumers, such as Plaintiff, in the marketing and advertising campaign described herein.

191. Defendants' conduct in connection with Invokamet was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous materiel facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of Invokamet.

192. As a result of these violations of consumer protection laws, Plaintiff have incurred and will incur; serious physical injury, pain, suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital and surgical expenses and other expense related to the diagnosis and treatment thereof, for which Defendants are liable. Wherefore, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory, treble

and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

Count 11 - Fraud

193. Plaintiff restates the allegations set forth above as if fully rewritten herein.

194. Defendants intentionally, willfully, knowingly, and fraudulently misrepresented to Plaintiff, his/her prescribing health care professionals, the health care industry, and consumers that Invokamet had been adequately tested in clinical trials and was found to be safe and effective as a diabetes treatment.

195. Defendants knew or should have known at the time they made their fraudulent misrepresentations that their material misrepresentations and omissions were false regarding the dangers and risk of adverse health events associated with use of Invokamet. Defendants made their fraudulent misrepresentations willfully, wantonly, and with reckless disregard and depraved indifference for the safety and well-being of the users of Invokamet, such as Plaintiff.

196. Defendants' fraudulent misrepresentations were made with the intent of defrauding and deceiving the health care industry and consumers, including Plaintiff and his/her prescribing health care professionals, so as to induce them to recommend, prescribe, dispense, or purchase Invokamet, despite the risk of severe life-threatening injury, which Defendants knew were caused by the product.

197. Defendants fraudulently and intentionally concealed material information, as aforesaid. Defendants knew that Invokamet was defective and unreasonably unsafe for its intended purpose and intentionally failed to disclose information regarding the true nature of the product's risks.

198. Defendants fraudulently and intentionally failed to disclose and warn of the severity of the injuries described herein, which were known by Defendants to result from use of Invokamet.

199. Defendants fraudulently and intentionally suppressed information about the severity of the risks and injuries associated with Invokamet from physicians and patients, including Plaintiff and his/her prescribing physicians, used sales and marketing documents that contained information contrary to Defendants' internally held knowledge regarding the aforesaid risks and injuries, and overstated the efficacy and safety of the Invokamet. For example:

a. Invokamet was not as safe and effective as other diabetes drugs given its intended use;

b. Ingestion of Invokamet does not result in a safe and more effective method of diabetes treatment than other available treatments;

c. The risks of harm associated with the use of the Invokamet was greater than the risks of harm associated with other forms of diabetes drug therapies;

d. The risk of adverse events with Invokamet was not adequately tested and was known by Defendants, but Defendants knowingly failed to adequately test the product;

e. Defendants knew that the risks of harm associated with the use of Invokamet was greater than the risks of harm associated with other forms of diabetes drug therapies, yet knowingly made material misrepresentations and omissions of fact on which Plaintiff relied when ingesting Invokamet;

f. The limited clinical testing revealed that Invokamet had an unreasonably high risk of injury, including Plaintiff's injuries, above and beyond those associated with other diabetes drug therapies;

g. Defendants intentionally and knowingly failed to disclose and concealed the adverse events discovered in the clinical studies and trial results;

h. Defendants had knowledge of the dangers involved with the use of Invokamet, which dangers were greater than those associated with other diabetes drug therapies;

i. Defendants intentionally and knowingly failed to disclose that patients using Invokamet could suffer heart attack, stroke, renal failure, renal impairment, renal insufficiency, ketoacidosis, and sequelae;

j. Invokamet was defective, and caused dangerous and adverse side effects, including the specific injuries described herein.

200. Defendants made the above misrepresentations before, during, and after FDA approval of Invokamet, and to date, continue to make such misrepresentations.

201. Defendants' misrepresentations were made through various methods, including but not limited to, Invokamet's published labeling and medication guide, medical literature, promotional materials directed at consumers, promotional materials directed at health care professionals, and documentation submitted in support of Invokamet's NDA.

202. Defendants had access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who ingest Invokamet, information that was not publicly disseminated or made available, but instead was actively suppressed by the Defendants.

203. Defendants' intentional concealment and omissions of material fact concerning the safety of Invokamet was made with purposeful, willful, wanton, fraudulent, and reckless disregard for the health and safety of Plaintiff, and with reckless intent to mislead, so as to cause Plaintiff's prescribing health care professionals to purchase, prescribe, and/or dispense Invokamet, and to cause Plaintiff to rely on Defendants' fraudulent misrepresentations that Invokamet was a safe and effective diabetes drug therapy.

204. At the time Plaintiff purchased and used Invokamet, Plaintiff was unaware that Defendants had made misrepresentations and omissions, and instead Plaintiff reasonably believed Defendants' representations to constitute true, complete, and accurate portrayal of Invokamet's safety and efficacy.

205. Defendants knew and had reason to know that Invokamet could and would cause serious personal injury to the users of the products, and that the products were inherently dangerous in a manner that exceeded any purported warnings given by Defendants.

206. In reliance on Defendants' false and fraudulent misrepresentations, Plaintiff was induced to use and in fact used Invokamet, thereby sustaining injuries and damages. Defendants knew and had reason to know that Plaintiff and his/her health care professionals did not have the ability to determine the true facts intentionally concealed and suppressed by Defendants, and that Plaintiff and his/her health care professionals would not have prescribed and ingested Invokamet if the true facts regarding the drug had not been concealed by Defendants.

207. During the marketing and promotion of Invokamet to health care professionals, neither Defendants nor the co-promoters who were detailing Invokamet on Defendants' behalf, warned health care professionals, including Plaintiff's prescribing health care professionals, that Invokamet caused or increased the risk of heart attack, stroke, renal failure, renal impairment, renal insufficiency and ketoacidosis.

208. Plaintiff reasonably relied upon Defendants' misrepresentations, where knowledge of the concealed facts was critical to understanding the true dangers inherent in the use of Invokamet.

209. Defendants willfully, wrongfully, and intentionally distributed false information, assuring Plaintiff, the public, Plaintiff's health care professionals, and the health care industry that Invokamet was safe for use as a means of diabetes treatment. Upon information and belief, Defendants intentionally omitted, concealed, and suppressed the true results of Defendants' clinical tests and research.

210. Defendants' conduct was intentional and reckless. Defendants risked the lives of consumers and users of Invokamet, including Plaintiff. Defendants knew of Invokamet's safety problems and suppressed this knowledge from the general public. Defendants' intentional and reckless conduct warrants an award of punitive damages.

211. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered personal and economic injuries. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

Count 12 – Violation of Consumer Protection Laws

212. Plaintiff restates the allegations set forth above as if fully rewritten here. 253. Plaintiff used Invokamet and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protections laws.

213. Defendants used unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, uses, benefits or quantities that they do not have:

b. Advertising goods or services with the intent not to sell them as advertised; and

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

214. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of Invokamet.

215. Defendants uniformly communicated the purported benefits of Invokamet while failing to disclose the serious and dangerous side effects related to the use of Invokamet and of the true state of Invokamet's regulatory status, its safety, its efficacy, and its usefulness. Defendants made these representations to physicians, the medical community at large, and to patients and consumers, such as Plaintiff, in the marketing and advertising campaign described herein.

216. Defendants' conduct in connection with Invokamet was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous materiel facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of Invokamet.

217. As a result of these violations of consumer protection laws, Plaintiff have incurred and will incur; serious physical injury, pain, suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital and surgical expenses and other expense related to the diagnosis and treatment thereof, for which Defendants are liable.

Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory, treble and punitive damages, together with interest, costs herein incurred, attorneys'

fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

DELAYED DISCOVERY

218. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's physicians and healthcare providers the true and significant risks associated with Invokamet.

219. As a result of Defendants' actions, Plaintiff and Plaintiff's physicians and healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the result of Defendants' acts, omissions, and misrepresentations.

220. The accrual and running of any applicable statute of limitations has been tolled by reason of Defendants' fraudulent concealment.

221. Each Defendant is equitably estopped from asserting any limitations defense by virtue of its fraudulent concealment and other misconduct as described in this Complaint.

PUNITIVE DAMAGES

222. The acts, conduct, and omissions of Defendants were willful and malicious. Defendants committed these acts with a conscious disregard for the rights, health and safety of Plaintiff and other Invokamet users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Invokamet. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants.

223. Prior to the manufacturing, sale, and distribution of Invokamet, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical,

mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using Invokamet.

224. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Invokamet and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Invokamet. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Invokamet knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

225. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

PRAYER FOR RELIEF

Plaintiff prays for relief and judgment against Defendants, and each of them, individually, jointly, and severally, as follows:

1. Judgment for Plaintiff and against Defendants;
2. Damages to compensate Plaintiff's injuries sustained as a result of the use of Invokamet for past and future loss of income proven at trial;
3. Physical pain and suffering of the Plaintiff; and any and all damages allowed under the law;
4. Pre and post judgment interest as the lawful rate;
5. Exemplary and punitive damages in an amount in excess of the jurisdictional limits, trebled on all applicable Counts;

6. A trial by jury on all issues of the case; and,

7. For any other relief as this court may deem equitable and just, or that may be available under the law of another forum to the extent the law of another forum is applied including but not limited to reasonable attorneys' fees and costs and expert fees.

DEMAND FOR A TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff demands a jury trial as to all issues and defenses.

Respectfully submitted,

MESTEMAKER & STRAUB

/s/ David K. Mestemaker (April 20, 2018)

David K. Mestemaker
Texas Bar No. 13974600
Federal ID: 14410
dkm@msandz.com
3100 Timmons Lane, Suite 455
Houston, Texas 77027
(713) 626-8900 Telephone
(713) 626-8910 Telecopier
ATTORNEY FOR PLAINTIFF